

Ninety-Eighth Legislature - First Session - 2003 Committee Statement LB 756

Hearing Date: February 13, 2003

Committee On: Health and Human Services

Introducer(s): (McDonald, Aguilar, Baker, Bourne, Burling, Byars, Combs, Connealy, Cudaback, Cunningham, Erdman, Hudkins, Jensen, Johnson, Jones, Kremer, Kruse, Mines, Mossey, Dw. Pedersen, D. Pederson, Preister, Price, Redfield, Schimek, Smith, Stuhr, Stuthman,

Synowiecki, Thompson, Tyson, Vrtiska, Wehrbein) **Title:** Adopt the Cancer Drug Repository Program Act

Roll Call Vote – Final Committee Action:

Advanced to General File

X Advanced to General File with Amendments

Indefinitely Postponed

Vote Results:

5 Yes Senator Jensen, Maxwell, Erdman, Johnson and Stuthman

No

Present, not voting

2 Absent Senator Byars and Cunningham

Proponents:Representing:Senator McDonaldIntroducerJoe SteeleSelf

Joni Cover Nebraska Pharmacists Association

Beverly Rippe Self

David Holmquist

David Buntain

Roger Keetle

American Cancer Society

Nebraska Medical Association

Nebraska Hospital Association

Opponents: Representing:

Neutral: Representing:

Dr. Richard Raymond Nebraska Health and Human Services System John Lindsay Nebraska Association of Trial Attorneys

Summary of purpose and/or changes: The bill adopts the Cancer Drug Repository Program Act. The bill defines terms. It requires the Department of Health and Human Services to establish a cancer drug repository to accept and dispense donated cancer drugs to Nebraska residents who meet state eligibility requirements.

The repository is restricted as follows:

- 1. only cancer drugs in their original sealed and unopened unit dose packaging;
- 2. no cancer drugs with an expiration date less than six months after the date of donation;
- 3. no drug may be accepted or dispensed if there is reason to believe that it is adulterated; and
 - 4. unused drugs under the Medicaid program may be donated to the repository.

Any person may donate cancer drugs to the drug repository program. They must be donated at a pharmacy, hospital, or nonprofit clinic that meets participation criteria for the program. Participation in the program is voluntary.

A pharmacy, hospital, or nonprofit clinic that meets eligibility standards may dispense donated drugs under the program to persons who meet state eligibility requirements or to other governmental entities and nonprofit private entities for dispensing.

Donated drugs may only be dispensed pursuant to a prescription issued by a health care professional. A pharmacy, hospital, or clinic that accepts donated drugs must comply with all applicable provisions of federal or state law pertaining to the storage and distribution of dangerous drugs and must inspect all drugs prior to dispensing. The pharmacy, hospital, or clinic may charge a handling fee. Donated drugs may no be resold.

The following persons or entities are immune from liability if they act in good faith in matters relating to donating, accepting, or dispensing drugs under the program: the department, the director of HHS, any cancer drug manufacturer, governmental unit, persons donating cancer drugs to the program, pharmacies, hospitals, nonprofit clinics, health care professionals that accept or dispense drugs under the program, and pharmacies, hospitals or nonprofit clinics that employ such health care professionals.

Cancer drug manufacturers are exempt from liability for injury, death or loss to persons or property for matters related to the donation, acceptance, or dispensing of a cancer drug manufactured by the manufacturer and donated under the program, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

The director of HHS, in consultation with the Board of Pharmacy, must adopt and promulgate rules and regulations under the program relating to:

- 1. eligibility criteria for pharmacies, hospitals, and nonprofit clinics;
- 2. standards and procedures for accepting, storing, and dispensing donated drugs;
- 3. standards and procedures for inspecting donated drugs;
- 4. eligibility standards based on economic need for persons to receive donated drugs;
- 5. an identification card to indicate eligibility under the program;
- 6. a form indicating understanding of immunity provisions of the act that must be signed by persons receiving donated drugs;
- 7. a minimum handling fee that may be charged to recipients of donated drugs to cover restocking and dispensing costs;
- 8. a list of drugs that the program will and will not accept for donation from individuals and a form to be completed by the person donating the drugs;
- 9. a list of drugs that the program will and will not accept from health care facilities; and 10. any other standards and procedures the board considers appropriate to carry out the act.

The act has an operative date of September 15, 2003.

Explanation of amendments, if any: The committee amendment (AM 727) becomes the bill. The amendment adopts the Cancer Drug Repository Program Act and defines terms. The amendment includes new definitions for department, health care facility, health clinic, pharmacy, physician office, and prescribing practitioner. It deletes definitions for health care professional and nonprofit clinic

The amendment establishes the cancer drug repository program and provides for the donation of cancer drugs to the program. Such drugs may be donated by any person or entity at a physician office, pharmacy, hospitals, or health clinic that elects to participate in the program and meets eligibility standards established by the Department of Health and Human Services Regulation and Licensure for such participation.

The amendment retains criteria for acceptance of donated cancer drugs under the program from the bill as introduced. The amendment requires compliance by participating physician offices, pharmacies, hospitals, and health clinics with all applicable state and federal law relating to the storage, distribution, and dispensing of such drugs. The amendment permits donated cancer drugs to be distributed to another participating physician office, pharmacy, hospital, or health clinic for dispensing.

The amendment revises immunity provisions. It provides immunity from civil or criminal liability or professional disciplinary action for any person or entity which acts with reasonable care in donating, accepting, distributing, or dispensing cancer drugs under the program. The donation of a cancer drug by a cancer drug manufacturer does not absolve the manufacturer of any criminal or civil liability that would have existed but for the donation, including but not limited to, liability for failure to transfer or communicate product or consumer information or the expiration date of the donated cancer drug.

The amendment deletes any eligibility or "means testing" requirement for persons who receive donated cancer drugs under the program.

Senator Jin	Jensen,	Chairperson	